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1

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/565,673	08/10/1990	JOHANNES C. VAN DER LAAN		8222

7590

05/02/2006

DEBRA J. GLAISTER PATENT AGENT  
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EXAMINER
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FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

07/565,673

Applicant(s)

VAN DER LAAN ET AL.

Examiner

Christian L. Fronda

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02/06/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 48, 50, 53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48, 50, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1652

### DETAILED ACTION

1. Claims 48, 50, 53, and 54 are pending and under consideration in this Office Action.
2. The rejection of claims 48, 50, 53, and 54 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of applicants' extensive claim amendments and arguments filed on 02/06/2006.

#### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 48, 50, 53, and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the following additional reasons.

Applicants' arguments filed 02/06/2006 have been acknowledged but are not persuasive. Applicants' position is that the claims as amended are limited to the wild-type alkaline serine protease of PB92 or its derivative PBT100, and that regulatory elements, promoter, and 5' and 3' non-coding flanking regions are described in the specification. The examiner appreciates applicants' arguments agrees that the specification describes the wild-type alkaline serine protease of PB92 or its derivative PBT100. However, the examiner respectfully disagrees for reasons of record as explained below that the regulatory elements, promoter, and 5' and 3' non-coding flanking regions of the gene encoding the wild-type alkaline serine protease of PB92 or its derivative PBT100 are adequately described in the specification.

As stated in the previous Office Action, gene elements which are not particularly described including the promoter, regulatory elements, and 5' and 3' flanking non-coding regions are essential to the function of the claimed invention since the claims recite a gene encoding a *Bacillus*

Art Unit: 1652

wild-type alkaline serine protease and the 5' and 3' flanking non-coding regions. Therefore, the structure of these gene elements which applicants considers as being essential to the function of the claim are not conventional in the art. There is no known or disclosed correlation between the coding region of the wild-type alkaline serine protease and the structure of the non-described promoter, regulatory elements, and 5' and 3' flanking non-coding regions of the gene. There is no additional disclosure of physical and/or chemical properties of these gene elements. In particular there is no disclosure of nucleotide sequence and structure of the 5' and 3' flanking non-coding regions.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of the gene elements including promoter, regulatory elements, and 5' and 3' flanking non-coding regions of the *Bacillus* wild-type alkaline serine protease.

Amending the claim to recite the phrase "an indigenous polynucleotide encoding the indigenous wild-type alkaline serine protease of PB92 or its derivative PBT100" may overcome the rejection.

### *Conclusion*

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N

Art Unit: 1652

Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

  
PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
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